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Arizona State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Proposed Statute Changes – 2005 Legislative Session

The Arizona State Board of Pharmacy is planning to introduce a bill in the 2005 legislative session that, if passed by the legislature and signed by the governor, will add a pharmacy technician member to the Board. A new pharmacist member position will also be added to maintain an odd number of Board members and prevent the possibility of deadlock because of tie votes. A majority of the Board believes this addition to be a logical step now that the Board licenses pharmacy technicians.

The bill also makes some long overdue changes to the processes the Board employs at conferences convened by the Board for discussion of pharmacy practice issues, which usually come to the attention of the Board as a result of consumer complaints. The formalized process will give the Board the opportunity to offer the conferee a consent agreement at the conclusion of the conference in those instances when the Board feels that remedial action such as additional continuing education (CE) or practice restrictions are necessary in order to protect the public health and safety. New definitions for advisory letters, letters of reprimand, and other cosmetic changes for disciplinary procedures are also included.

Housekeeping changes that include clarification of how the Board selects the executive director and the process for replacing the executive director in certain specific circumstances are in the bill. The bill also explicitly states that the deputy director would serve as interim acting executive director in these specified cases.

The bill adds reporting requirements that practitioners and permit holders must adhere to in cases where incompetence or unprofessional conduct are observed. Such observations will be required to be reported to the Board and the requirements are similar to existing legislation currently in place for most of the other Arizona health care regulatory boards.

Updates to various statutory definitions are also included and some of these will clarify the terms and processes for electronic transmission of prescriptions.

The Arizona criminal statutes and Controlled Substances Act are also being updated by adding lists of new chemical entities to the various controlled substances lists and by reducing the maximum amount of precursor chemicals such as pseudoephedrine that can be sold in a single transaction from 24 grams to 9 grams in order to more accurately mirror the current federal statutes and restrictions.

All of the proposed changes are available for review on the Board of Pharmacy's Web site at www.pharmacy.state.az.us/link62.htm. Please feel free to contact myself, Cheryl Frush, or our rule writer, Dean Wright, at rxcop@cox.net with your comments and suggestions.

Patient Counseling Task Force

A task force of community and hospital practitioners and other interested parties recently spent considerable time reviewing the patient counseling regulations in an attempt to simplify them and to remove barriers, real or imagined, from our current patient counseling regulations. The greatest barrier to effective counseling was perceived to be the current requirements for pharmacists to counsel on drugs that have been previously dispensed to patients such as updated prescriptions after one year and transfers from other pharmacies. The members of the Patient Counseling Task Force also felt that documentation of both acceptance as well as refusal of oral consultation by the patient should be documented routinely as a consistent procedure. New proposed rules will likely be forthcoming. Look to the Board Web site for updates on this issue in the coming months.

National Pharmacy Compliance News

(Applicability of the contents of articles in the National Pharmacy Compliance News to a particular state or jurisdiction should not be assumed and can only be ascertained by examining the law of such state or jurisdiction.)

New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlafaxine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

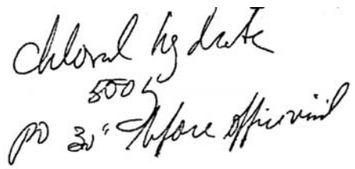
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol ("), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/698-6227 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE™, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

Disciplinary Actions – Board of Pharmacy (since July 2004 Newsletter*)*

Notice: *Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (board).*

Howard G. Jones, RPh – 15 hours of CE, 400 hours community service, six (6) months suspension, and five (5) years probation and Pharmacists Assisting Pharmacists of Arizona (PAPA) substance abuse contract: Controlled Substance violations, substance abuse.

Jonathan Corey Ray, RPh – Six (6) months suspension and five (5) years probation and PAPA substance abuse contract: Controlled Substance violations, substance abuse.

Bereket Gebre-Egziabher, RPh – Censure, eight (8) hours of CE, and $1,000 civil penalty: Failure to provide oral consultation on a new prescription.

Joel Gibson, RPh – Censure, eight (8) hours of CE, and $1,000 civil penalty: Prescription error.

Michael Biegun, RPh – Six (6) months probation and additional eight (8) hours of CE: Failure to provide oral consultation on a new prescription.

K-Mart Corporation #7236, non-prescription retail permit – $520 civil penalty and one (1) year probation: Outdated over-the-counter drugs.

Caryn Trotta, Intern License – Six (6)-month to two (2)-year suspension and five (5)-year PAPA substance abuse contract: Controlled Substance violations.

Kanu Patel, RPh – Six (6) months probation and may not serve as pharmacy preceptor: Incorrect directions on new prescription label.

Disciplinary Actions – Other Health Care Practitioner Boards

Michael R. Templeton, DDS – Three (3) years probation and prescription monitoring, effective March 29, 2004.

Lawrence E. Pritchard, MD – Summary Suspension until formal hearing, effective June 4, 2004.

Timothy Fowler, MD – License inactivated, effective May 7, 2004.

Jack I. Dodge, MD – License suspended until further notice, effective June 15, 2004.

Abedon Saiz, MD – Stayed revocation and ten (10) years probation, effective June 15, 2004.

John Paul Utz, MD – voluntary surrender of license, effective May 12, 2004.

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The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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